Docket No. DEP0546

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Serhan et al.	Group Art Unit:	3732
Serial No.:	09/822,126	Examiner:	Manahan, Todd E.
Filed:	March 30, 2001		
Title:	Intervertebral Connection System		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF HASSAN SERHAN UNDER 37 CFR 1.131

I, Hassan Serhan, declare and state that:

1. I am Director of Research at DePuy AcroMed Inc. in Raynham, MA, and have held this position since 1999.

2. I received a Ph.D. in Mechanical Engineering from the University of Buffalo.

3. I am a co-inventor of the above captioned application and am aware that the present invention relates to a fabric-based conformable ligament.

4. Attached hereto as Exhibit I is a copy of an Invention Disclosure No. 2001-02, entitled "Spine Ligament Prosthesis and Method of Implantation, that I signed on January 8, 2001. On the first page of the section entitled "DETAILED DESCRIPTION OF THE INVENTION", we disclose that the ligament of the present invention may be made of absorbable materials such as polymers of lactic and glycolic acids, and that it may be in the form of a "braided tow". Figure 2 provided on that same page shows a woven ligament. A braided tow is a fabric.

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that

these statements were made with knowledge that will false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent application and any patent issuing thereon.

Respectfully submitted,

Hassan Serhan

8-22-03 (date)

Disclosure No. 2001-02 rec'd 11/9/01
(For Patent Dept. Use)

INVENTION DISCLOSURE

1. **TITLE OF INVENTION** **Spine Ligament Prosthesis and Method of Implantation**

2. **INVENTORS** (Person or persons who had the main idea or ideas relating to the invention.)

Full Name:	Hassan Serhan	Michael Andrew Slivka	
Residence:	27 Forest Edge Rd.	290 Plain Street	
	S. Easton, MA 02375	Taunton, MA 02780	
Citizen of:	USA	USA	
Bus. Phone:	(508) 828-3722	(508) 828-3639	
Supervisor:	Alex Dinello	Hassan Serhan	
Signature:			

(Use additional pages if there are more than three inventors.)

3. **PUBLIC USE**

Has the invention been in public use (non-confidential use outside BMC) for other than experimental purposes? (Scale up, product development, or any other public use aimed at bringing a product to market are not considered experimental.)
____**NO**_____ If "yes", indicate the date of the first such use: _____

4. **SALE**

Has a product employing the invention been sold or offered for sale? ___**NO**___
If "yes", indicate the date of first such sale or offer for sale:_____

5. **PUBLICATION**

A. Has this invention been described in a printed publication (newsletter, patent journal article, etc.)? ___**NO**____ If "yes", indicate earliest date of publication _____; earliest date of submission of information to a publisher _____; and the name of the publication _____
_____.

B. Has the invention been shown, described or demonstrated to persons who are not obligated to keep the invention secret (such as vendors or consultants)?
_____**NO***_____ If "yes", indicate the earliest date of such a showing, description or demonstration _____, and to whom (include country of recipient of information)
* Idea was disclosed to persons under confidentiality agreement: Dr. Gary Lowery (Baltimore, July 27, 2000) and Dr. Behrooz Akbarnia (Raynham, September 9, 2000).

6. CONCEPTION

Invention conceived (realization of problem and solution) on __July 1, 1999____,
In which country was the invention conceived? _____**USA**_____
Earliest witnessed and dated written evidence of conception ____New Idea _____
_Acknowledgement Form, Idea #438__ dated ____July 20, 1999_____.

7. ACTUAL REDUCTION TO PRACTICE

Has invention actually been fully constructed or demonstrated? _____**NO**____
If "yes", indicated completion date _____. Earliest witnessed and dated written evidence of a demonstration of the invention is
_____dated _____.

8. PROBLEM OVERCOME BY INVENTION *

Current spine fusion procedures rely heavily on the use of posterior fixation to achieve the necessary stability and rigidity to obtain successful clinical results. Implantation of posterior instrumentation necessarily involves removing important musculoskeletal elements. The proposed invention would minimize the damage caused to these supporting elements, reduce surgery time, reduce time for rehabilitation, and therefore reduce greatly the cost of the treatment.

9. PURPOSE OF THE INVENTION (brief) *

The proposed invention is intended to act as a temporary stabilization system for spine fusion procedures. The invention is particularly useful for augmenting single or multi-level anterior interbody fusion. Once fusion has been achieved, the device serves no purpose.

10. DESCRIPTION OF THE INVENTION (brief) *

The invention consists of a longitudinal element and a means of securing the longitudinal element to adjacent vertebral bodies. The device provides temporary stabilization until fusion can be achieved and therefore may be composed of an absorbable material. The securing elements preferably offer a means of providing tension to the longitudinal element. The device preferably has a very low profile so that it does not impinge upon adjacent blood vessels. The method of implantation of the device is preferably simple and rapid.

11. BRIEF DESCRIPTION OF STATE OF THE ART *

Current spine fusion augmentation consists primarily of antero-lateral bone screw/rod or plate systems and postero-lateral pedicle screw/rod or plate systems. Several anterior fixation designs have been described in prior inventions. Many anterior cruciate ligament repair devices have been described.

12. DIFFERENCES BETWEEN PRIOR ART AND THIS INVENTION *

This invention provides a combination implant and insertion method that is simple, allows for quick implantation and provides rigid, temporary anterior tensile support to complement an anterior interbody fusion procedure. Prior art describes devices to regenerate ligamentous structures (ACL), in a plate/screw form, or as an integral part of a disc prosthesis. The prior art lacks the ease of use and functionality for augmenting ALIF procedures provided by this invention.

13. DETAILED DESCRIPTION

Questions marked with "*" may be answered in more detail on attached pages. Detailed answers to questions 11 and 12 may be submitted at a later date; however, consideration of most Invention Disclosures will be delayed until these two questions are answered in detail. An answer to question 11 should include copies of patents, journal articles and product literature giving evidence of the state of the prior art. The typical "introduction" portion of a scientific paper is a good format to use in making a detailed response to questions 11 and 12.

Please indicate the number of pages attached to this form at the time of submission: 7 13 MAS 1-8-01

14. **WITNESSES:** (If possible, obtain signature of person(s) who witnessed and understood conception and test demonstration of items 5 and 6 above.)

1. The invention was first explained to me by the above described inventor(s) on 1/8/01, and it is understood by me.

[signature] (Signature of Witness) 1/8/01 (Date of Signature)

2. The invention was first explained to me by the above described inventor(s) on 8 Jan 01, and it is understood by me.

[signature] (Signature of Witness) 8 Jan 01 (Date of Signature)

DETAILED DESCRIPTION OF THE INVENTION

A first embodiment of the invention consists of a woven fabric strip (1) that has an integral anchor/fastener (2) at each end (Figure 2). In the example below, the implant is applied to a single level spine fusion procedure after discectomy and insertion of an interbody device (Figure 1). First the adjacent vertebral bodies are prepared to receive the implant using a punch device (3) (Figure 3). Then an implant is affixed to the insertion tool (4) by inserting the prong tips (5) into the device anchors (Figure 4), which are partially cannulated. The implant and inserter are designed such that upon final insertion (Figures 5 and 6), the anchors are buried in the vertebral body to minimize profile and a residual tension is present in the woven strip. This procedure requires only two steps: punching holes in the vertebral body and inserting the implant, thereby making it simple and rapid. This is a very attractive feature with spine fusion procedures which can be very lengthy.

The implant material may consist of a nonabsorbable medical polymer such as polyester or nylon. However, since the device is only temporarily necessary until fusion is achieved, an absorbable material, such as polymers of lactic and glycolic acids may be preferred. The woven strip is integrated with the anchors preferably in a molding process. Thus the device is preferably a one-piece implant.

The longitudinal member may consist of other forms such as a braided fiber tow, solid member, or fiber-reinforced composite. The bone anchor may be any design known in the art, including winged, barbed or screw-in mechanisms.

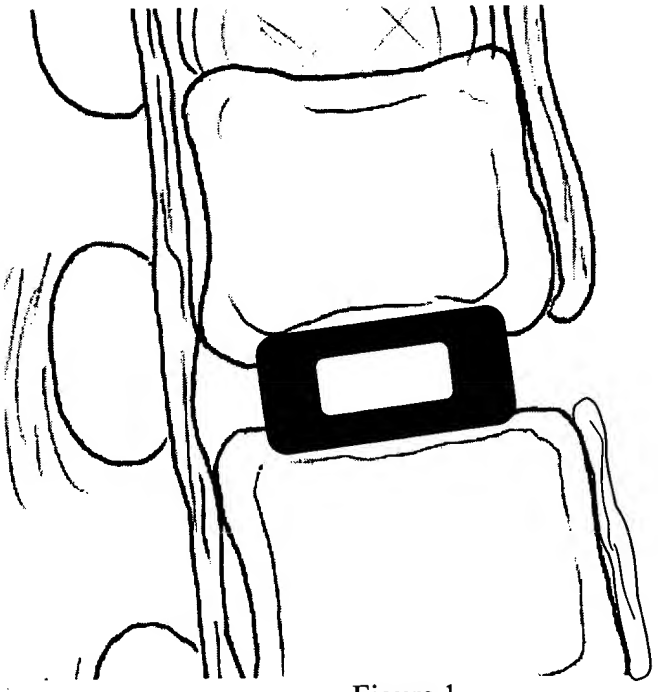

Figure 1

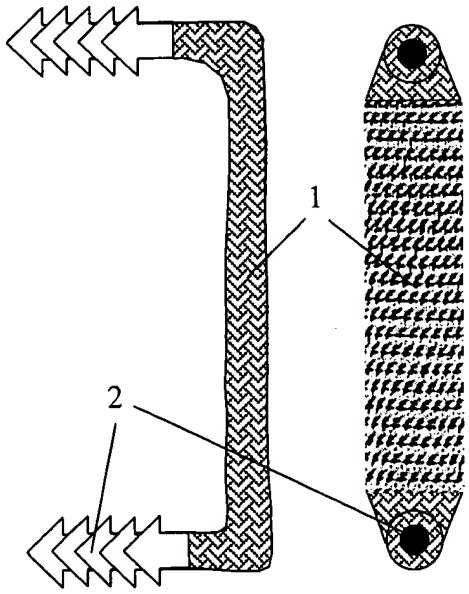

Figure 2

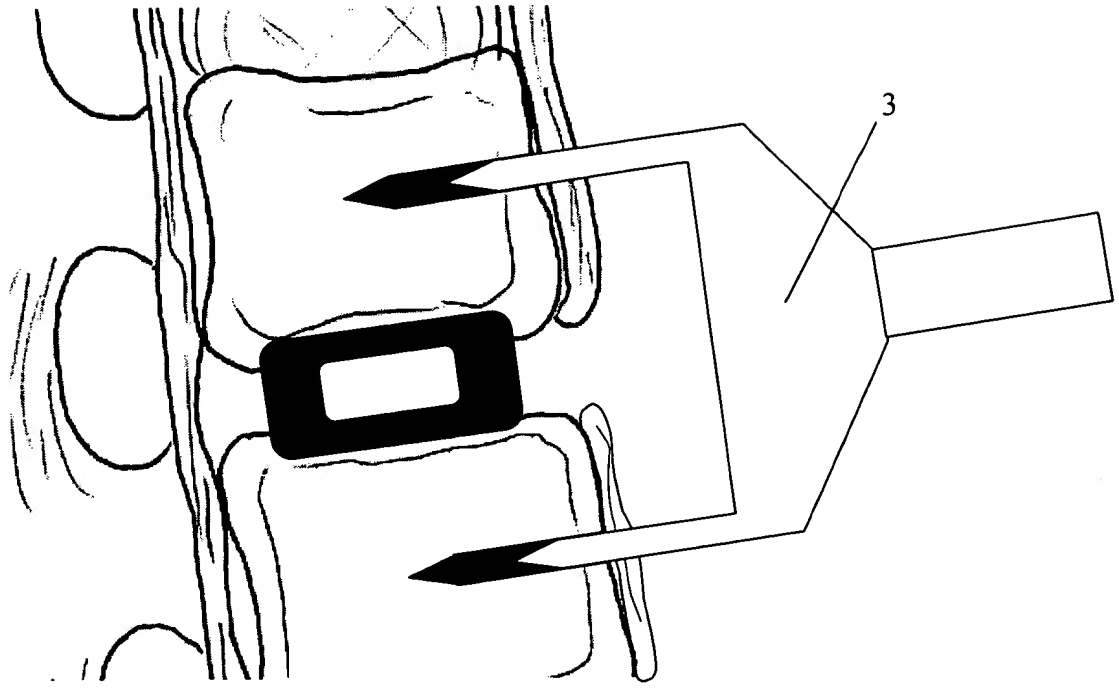

Figure 3

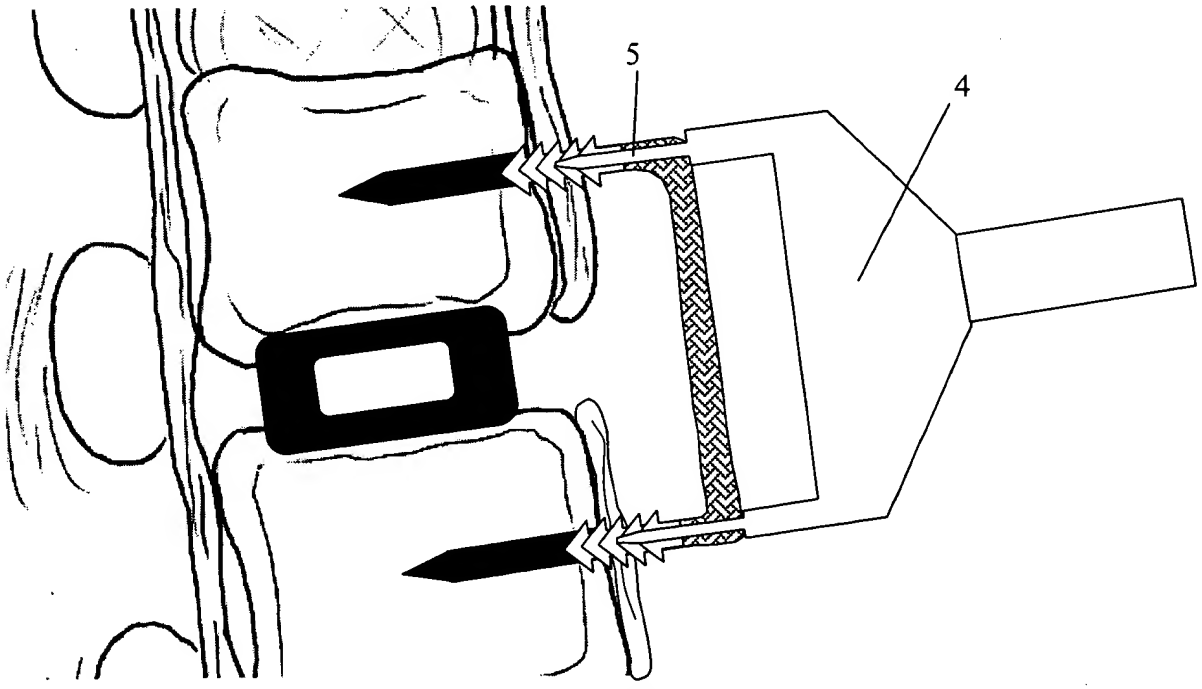

Figure 4

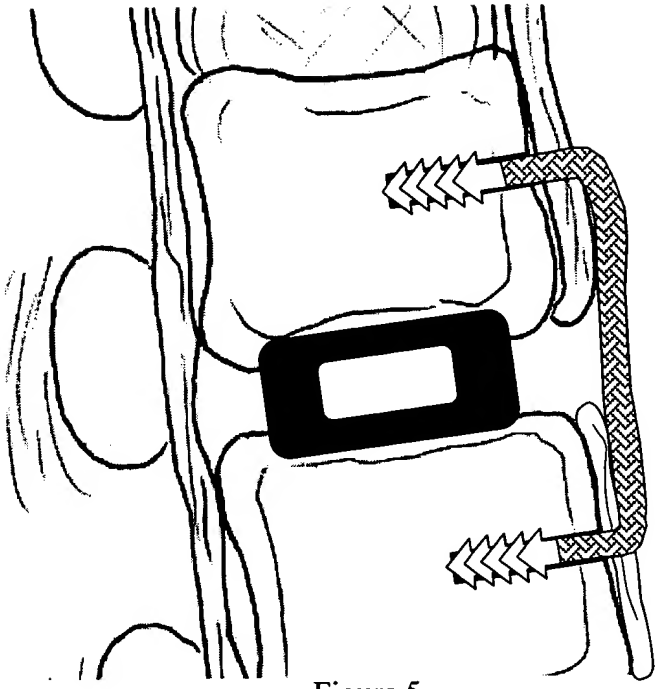

Figure 5

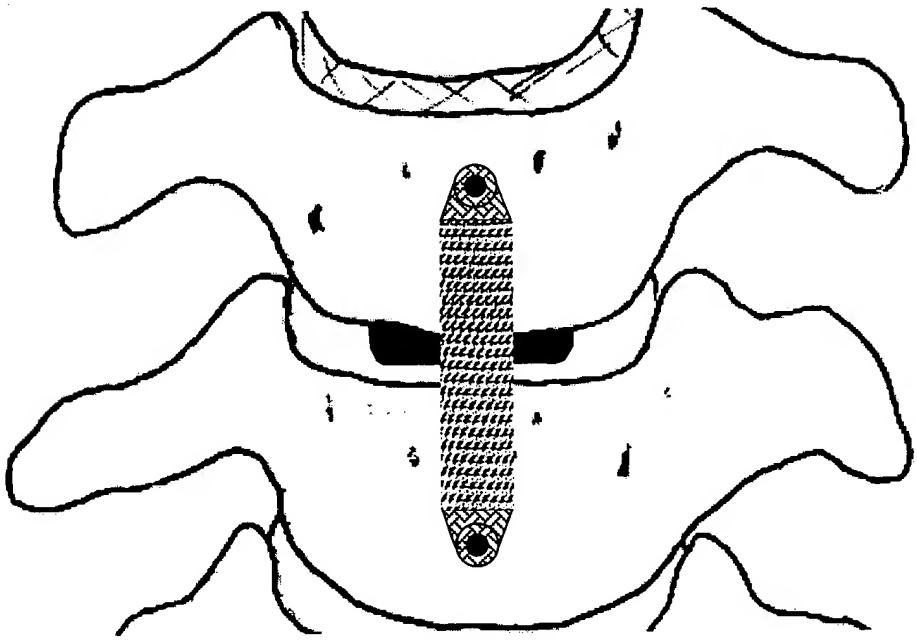

Figure 6

In another embodiment of the invention, a woven fabric strip (**6**) has two integral anchor/fasteners (**7**) at one end (Figure 8). A separate fastener (**8**) is used to secure the woven strip at multiple locations. In the example below, the implant is applied to a two level spine fusion procedure after discectomy and insertion of two interbody devices (Figure 7). First the top (or bottom) vertebral body is prepared to receive the implant using a punch device (**9**) (Figure 9). Then the implant is affixed to the insertion tool (**10**) by inserting the prong tips (**11**) into the device anchors (Figure 10), which are partially cannulated. Upon insertion (Figure 11), the anchors are buried in the vertebral body to minimize profile. The next vertebral body is prepared by first inserting the punch through the woven strip at the desired location, then applying a tension to the strip, then punching into the bone to prepare for the secondary fastener (Figure 12). The secondary fastener is applied in the same way as the first anchors. These steps are repeated until the implant has been secured to each level (Figures 13 and 14).

Material and alternative device considerations are the same as for the first embodiment described above. However, the secondary attachment device for this example may preferably be a bone screw to ensure optimal securing of the implant.

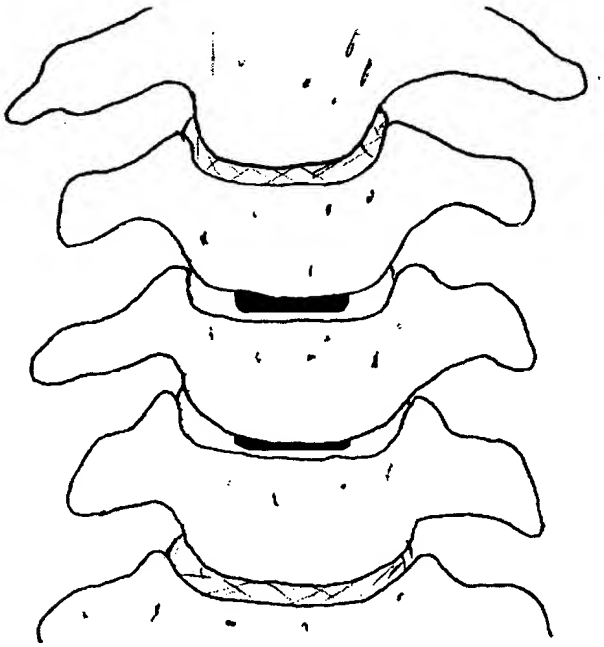

Figure 7

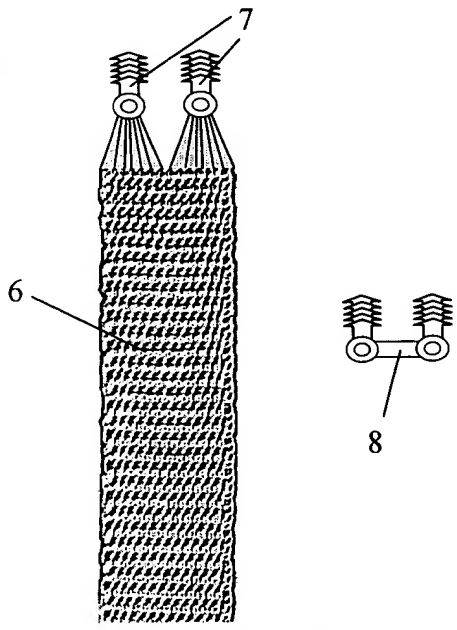

Figure 8

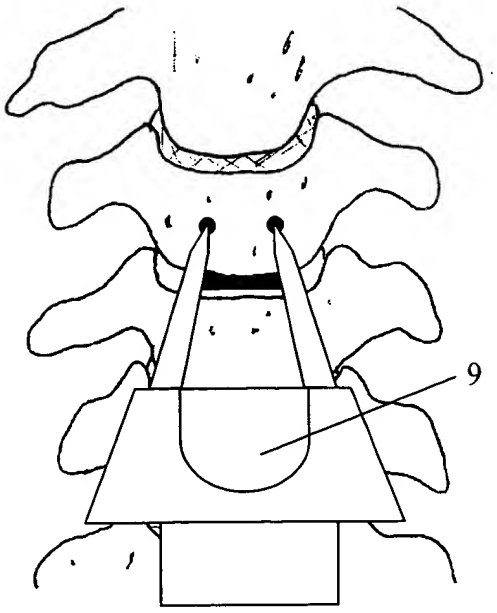

Figure 9

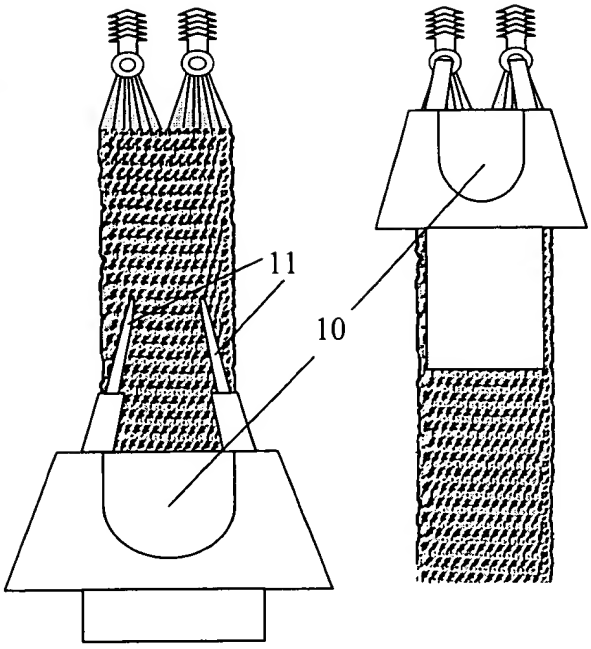

Figure 10

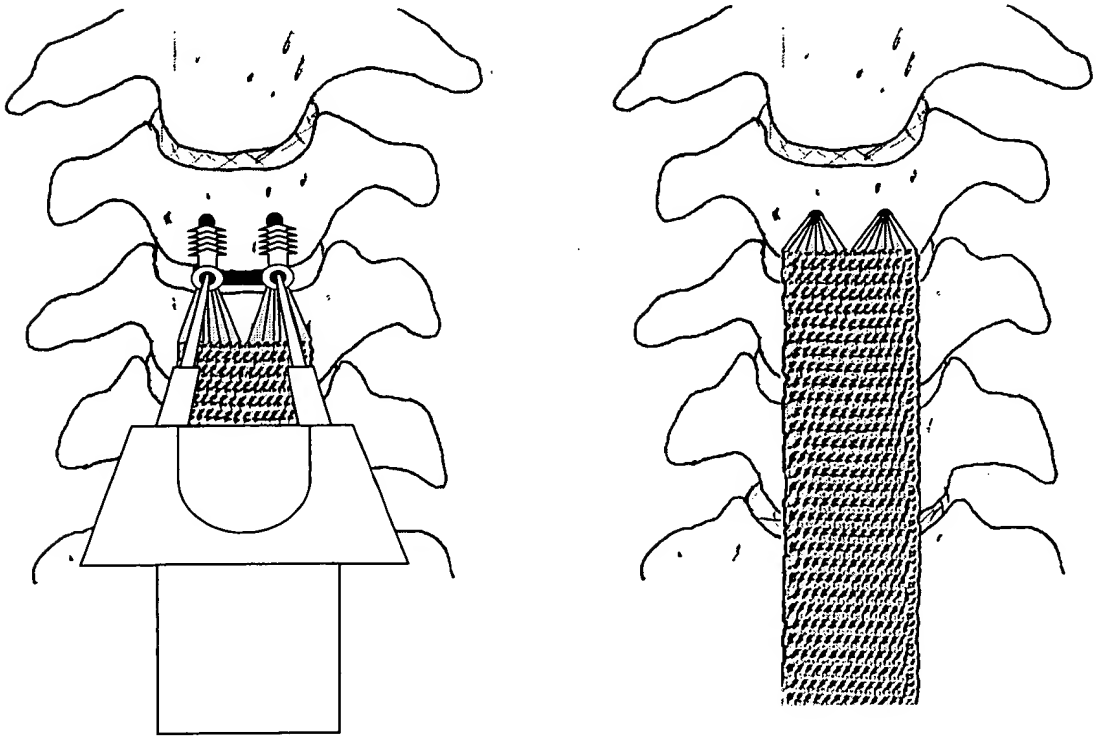

Figure 11

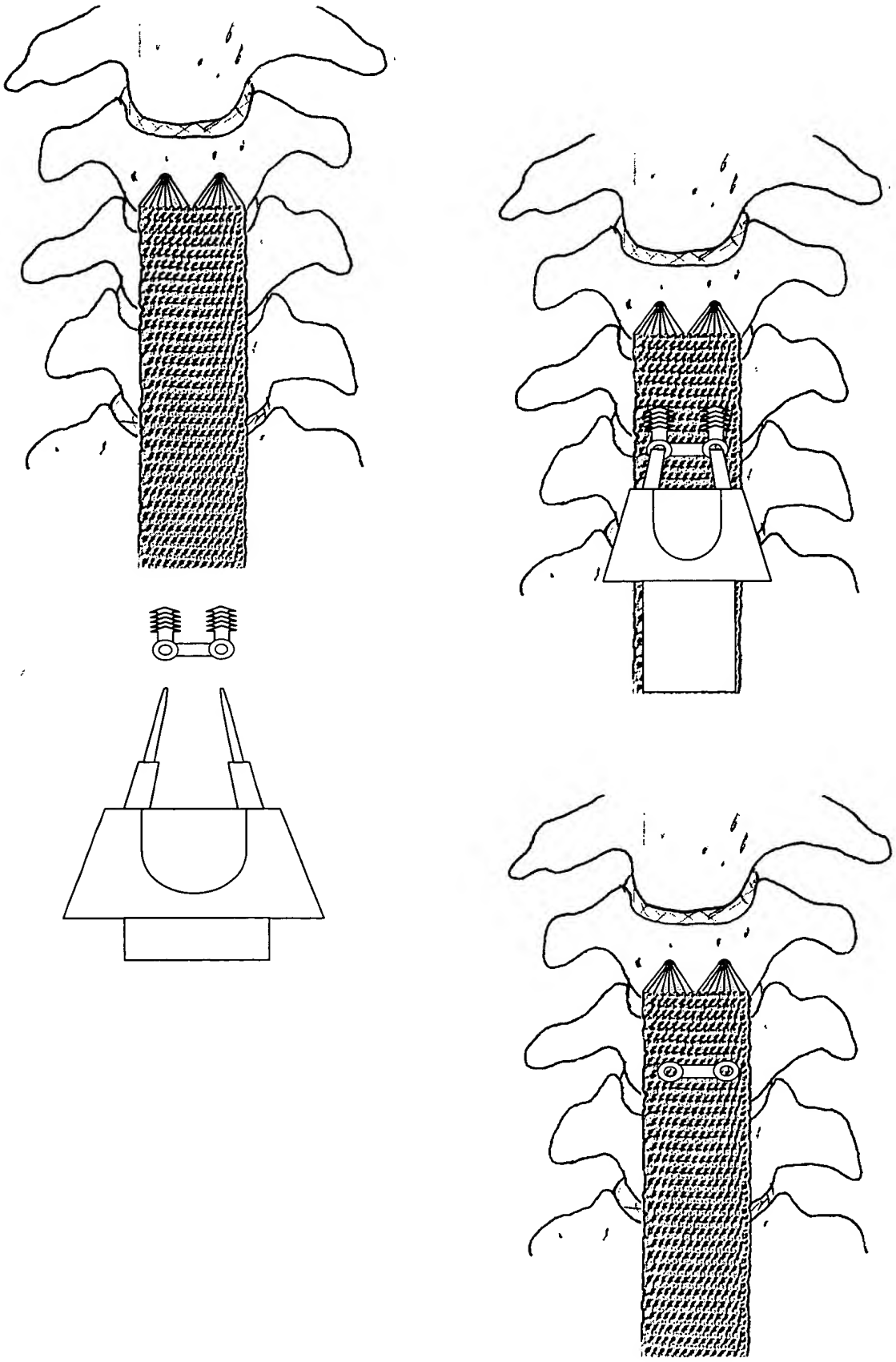

Figure 12

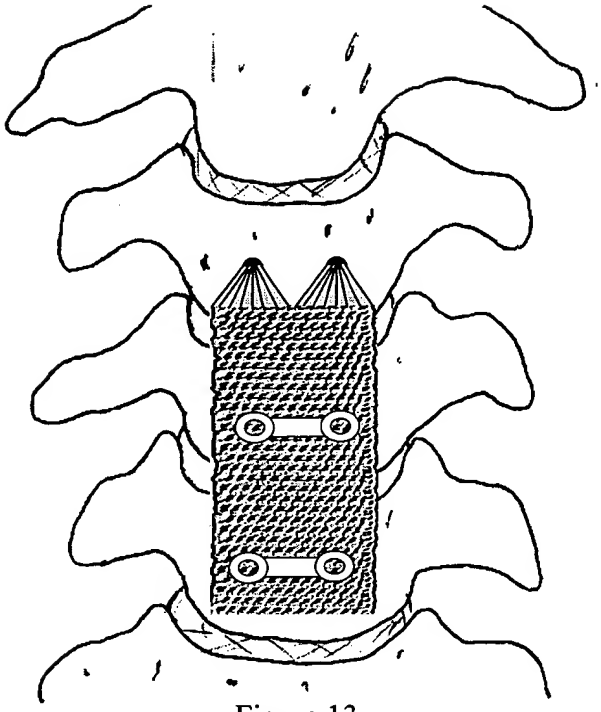

Figure 13

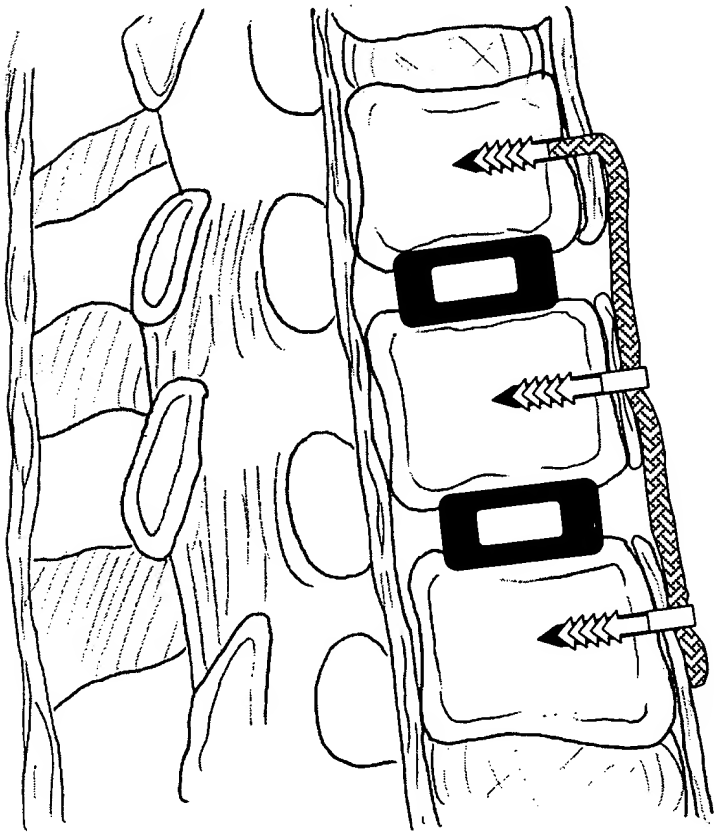

Figure 14